

In the Claims

This listing of claims will replace all prior versions, and listings, of claims in the application:

Listing of Claims

1. (Currently Amended) A pharmaceutical composition for use as an immunostimulant comprising a polycationic carbohydrate or a pharmaceutically acceptable derivative thereof, wherein the polycationic carbohydrate comprises a water-soluble alkylated chitosan, or a pharmaceutically acceptable salt or derivative thereof, or a mixture thereof a ~~cationic polypeptide, cationic polyamino acid, a quaternary ammonium compound or a mixture thereof, for use as an immunostimulant.~~

2. (Currently Amended) A ~~The~~ polycationic carbohydrate ~~according to~~ of claim 1 ~~where~~ wherein the polycationic carbohydrate comprises is a water-soluble alkylated chitosan selected from the group consisting of ~~derivative or a salt thereof, such a~~ trimethyl chitosan chloride, N-carboxymethyl chitosan and polyethylene glycol chitosan.

3. (Currently Amended) A ~~The~~ polycationic carbohydrate ~~according to~~ of claim 2 ~~"1" in which~~ wherein the alkylated chitosan is trimethylchitosan.

~~4. (Currently Amended) A The pharmaceutical composition of claim 1, further comprising a biologically active agent which is capable of generating a protective immune response in an animal, and a polycationic carbohydrate according to claim 1.~~

5. (Currently Amended) A ~~The~~ pharmaceutical composition ~~according to claim 4 of~~ claim 1 further comprising a cationic polypeptide, cationic polyamino acid, a quaternary ammonium compound or a mixture thereof ~~which further comprises a diluent or carrier.~~

6. (Currently Amended) A ~~The~~ pharmaceutical composition ~~according to~~ of claim 5 ~~"1" which comprises particles comprising~~ further comprising a first material capable of forming particles, wherein the pharmaceutical composition is in the form of particles

(i) ~~a biologically active agent which is able to produce an immune response in an animal to which it is administered;~~

(ii) ~~a first material capable of forming particles; and~~

(iii) ~~a polycationic carbohydrate according to claim 1.~~

7. (Withdrawn) A pharmaceutical composition comprising particles, each particle comprising

(i) a biologically active agent which is able to produce an immune response in an animal to which it is administered;

(ii) a first material capable of forming particles; and

(iii) one or more polycationic carbohydrates which have immunostimulant properties, wherein polycationic carbohydrate is distributed throughout the particle including at the surface.

8. (Withdrawn) A composition according to claim 7 wherein the polycationic carbohydrate comprises an immunostimulant which is a chitin derivative, a cationic polypeptide, a cationic polyamino acid, a quaternary ammonium compound or a mixture thereof.

9. (Withdrawn) A composition according to claim 8 wherein the polycationic carbohydrate comprises a chitin derivative.

10. (Withdrawn) A composition according to claim 9 wherein the chitin derivative is chitosan, chitosan chloride, or chitosan glutamate or a polycationic carbohydrate according to claim 2.

11. (Currently Amended) A ~~The~~ composition ~~according to~~ of claim 6 wherein the ~~particle comprises~~ particles comprise microspheres, microparticles or liposomes.

12. (Currently Amended) A The composition ~~according to~~ of claim 11 wherein the ~~particle comprises a microparticle~~ particles are microparticles.

13. (Currently Amended) A The composition ~~according to~~ of claim 6 wherein the first material capable of forming particles is a polymeric material which has a molecular weight of 100kDa or more.

14. (Currently Amended) A The composition ~~according to~~ of claim 6 wherein the first material capable of forming particles comprises poly-(L-lactide).

15. (Currently Amended) A The composition ~~according to~~ of claim 6 wherein the ratio of the first material capable of forming particles to the polycationic carbohydrate is from 99:1 to 9:1 w/w.

16. (Currently Amended) A The composition ~~according to~~ of claim 6 "37" wherein the biologically active agent is capable of generating a protective immune response against tetanus, diphtheria, or *Yersinia pestis*.

17. (Currently Amended) A The composition ~~according to~~ of claim 16 wherein the biologically active agent comprises a combination of the V antigen of *Y. pestis* or an immunologically active fragment thereof, and the F1 antigen of *Y. pestis* or an immunologically active fragment thereof.

18. (Currently Amended) A The composition ~~according to~~ of claim 6 which is adapted for intranasal application.

19. (Currently Amended) A The composition ~~according to~~ of claim 6 which is adapted for parenteral administration.

20. (Currently Amended) A The composition according to of claim 6 which further comprises a chemical compound selected from the group consisting of:

- (A) a polyamino acid,
- (B) a vitamin or vitamin derivative,
- (C) cationic pluronics,
- (D) a clathrate,
- (E) a complexing agent,
- (F) cetrimides,
- (G) an S-layer protein, or
- (H) methyl-glucamine.

21. (Currently Amended) A The composition according to of claim 20 "1" which further ~~comprises~~ comprising a cationic pluronic.

22. (Currently Amended) A The composition according to of claim 21 20 which comprises ~~nanospheres~~ particles of a the cationic pluronic which are surface modified with ~~chitosan~~ the polycationic carbohydrate.

23. (Currently Amended) A method for producing a pharmaceutical composition, which ~~method~~ comprises encapsulating a biologically active agent in a first material, in the presence of a the polycationic carbohydrate according to of claim 1.

24. (Withdrawn) A method for producing a pharmaceutical composition, which method comprises forming an emulsion of a biologically active agent and a first polymeric material, in the presence of an immunostimulant polycationic carbohydrate, and dropping the resultant emulsion into a secondary aqueous phase which also contains an immunostimulant polycationic carbohydrate.

25. (Withdrawn) A method according to claim 24 wherein the immunostimulant polycationic carbohydrate is a chitin derivative, cationic polypeptide, cationic polyamino acid, a quaternary ammonium compound or a mixture thereof.

26. (Withdrawn-Currently Amended) A method according to claim 25 wherein the polycationic carbohydrate is chitosan, chitosan chloride, chitosan glutamate or a water-soluble alkylated chitin derivative according to claim 2 or claim 3.

27. (Withdrawn) A method for producing a pharmaceutical composition which method comprises forming a microsphere, depositing a layer of polycationic carbohydrate thereon, and thereafter adsorbing a biologically active agent.

28. (Withdrawn) A method according to claim 27 wherein the immunostimulant polycationic carbohydrate is a chitin derivative, cationic polypeptide, cationic polyamino acid, a quaternary ammonium compound or a mixture thereof.

29. (Withdrawn-Currently Amended) A method according to claim 28 wherein the polycationic carbohydrate is chitosan, chitosan chloride, chitosan glutamate or a water-soluble alkylated chitin derivative according to claim 2 or claim 3.

30. (Withdrawn) A method of protecting an animal against a pathogen, said method comprising administering to said animal, a protective agent which is able to stimulate the animal's immune system to produce a response which is protective against said pathogen, and an immunostimulant comprising a polycationic carbohydrate according to claim 1.

31. (Withdrawn) A method of protecting an animal against a pathogen, said method comprising administering to said animal, a protective agent which is able to stimulate the animal's immune system to produce a response which is protective against said pathogen, in the form of a composition according to claim 6.

32. (Withdrawn) A method according to claim 30 wherein the protective agent which is able to stimulate the animal's immune system to produce a response which is protective against said pathogen, and an immunostimulant comprising a polycationic carbohydrate is applied parenterally or to a mucosal surface.

33. (Withdrawn) A method according to claim 32 wherein the protective agent and immunostimulant are applied to a mucosal surface.

34. (Withdrawn) A method according to claim 33 wherein said mucosal surface is an intranasal surface.

35. (Withdrawn) The use of a polycationic carbohydrate or a pharmaceutically acceptable derivative thereof according to claim 1 as an immunostimulant, in the preparation of a vaccine for use in prophylactic or therapeutic treatment.

36. (New) The composition of claim 6, wherein the polycationic carbohydrate is distributed throughout the particles including at the surface.

37. (New) The composition of claim 6, which further comprises a biologically active agent which is able to produce an immune response in an animal to which it is administered.

38. (New) A pharmaceutical vaccine composition for use as an immunostimulant comprising a polycationic carbohydrate, wherein the polycationic carbohydrate comprises a water-soluble alkylated chitosan, or a pharmaceutically acceptable salt or derivative thereof, or a mixture thereof; and

a first material capable of forming particles, wherein the pharmaceutical vaccine composition is in the form of particles; and

wherein the polycationic carbohydrate is distributed throughout the particles including at the surface.

39. (New) A pharmaceutical vaccine composition for use as an immunostimulant comprising a polycationic carbohydrate, wherein the polycationic carbohydrate comprises a water-soluble alkylated chitosan, or a pharmaceutically acceptable salt or derivative thereof, or a mixture thereof; and

a first material capable of forming particles; and

a cationic pluronic; wherein the cationic pluronic is in the form of particles, and surfaced modified with the polycationic carbohydrate.